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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09 724,380 | 11 28 2000 | Vincent J. Miles | 7960-147 | 9424 |

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EXAMINER

GUZO, DAVID

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1636

DATE MAILED: 09 24 2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,380

Applicant(s)

MILES ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 3,8-10 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 18 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) 8-10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s) 14
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: Handwritten signature

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Detailed Action

The examiner attempted to contact the attorney of record in order to inquire whether a Terminal disclaimer could be submitted in the case so as to obviate the double patenting rejection but the attorney of record did not return the call.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 3 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18, 19, 27, 30-36 of copending Application No. 10/104,611 (hereafter the '611 application) in view of Draper et al.

Applicants claim a method for screening for a nucleic acid capable of inhibiting translation of a HAV nucleic acid sequence containing a IRES element, said method comprising contacting said nucleic acid sequence with a test oligonucleotide complementary to at least a portion of said IRES wherein the ability of the test oligonucleotide to inhibit translation of the viral nucleic acid is detected by contacting the test sequence with a construct comprising the IRES element operably linked to a

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reporter gene and measuring and comparing the level of reporter translation product (protein) in the mixture vs. a control in the absence of the test oligonucleotide.

The '611 application broadly recites a method for screening for any potential antiviral agent (active against a viral (HAV) IRES element) which inhibits translation of a reporter gene operably linked to the IRES element comprising the same method steps and using any of several known reporters. The '611 application does not specifically recite a method for screening for a **nucleic acid** capable of inhibiting translation of a reporter by binding to a HAV IRES element.

Draper et al. (U.S. Patent 5,248,670, issued 9/28/93, filed 2/26/90, see whole document, particularly column 3) recites the well known activities of antisense oligonucleotides as inhibitory agents for use against viruses such as HSV, EBV, CMV, etc.

The ordinary skilled artisan, seeking to screen for nucleic acid inhibitors capable of inhibiting HAV IRES elements would have been motivated to use the teachings of the claims in the '611 application on methods of screening for any potential anti-HAV agent capable of interacting with a HAV IRES element and screen for nucleic acid inhibitors because Draper et al. notes that nucleic acids complementary to viral sequences can serve as potent inhibitors of viral activity. It would have been obvious for the ordinary skilled artisan to screen for nucleic acid inhibitors complementary to the IRES elements because Draper et al. indicates that nucleic acid sequences (antisense) can be effective inhibitors of viral activity. With regard to the specific reporter genes recited in the '611 application, it is noted that the instant claim recites use of any reporter gene and hence

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encompasses the recited reporters. Given the teachings of the claims in the '611 application and the level of skill of the ordinary skilled artisan at the time the invention was made, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

This is a provisional obviousness-type double patenting rejection.

Claim 3 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6 and 14 of U.S. Patent No. 5,738,985 (hereafter the '985 patent) in view of Draper et al.

Applicants' invention is as described in the above provisional obviousness type double patenting rejection of claim 3 over the '611 application.

The '985 patent broadly claims a method for screening for any potential antiviral agent (active against a viral (HAV) IRES element) which inhibits translation of a reporter gene operably linked to the IRES element, said method comprising the same steps. The '985 patent does not specifically recite a method for screening for a nucleic acid capable of inhibiting translation of a reporter by binding to a HAV IRES element.

Draper et al. (Cited above) recites the well known activities of antisense oligonucleotides as inhibitory agents for use against viruses.

The ordinary skilled artisan, seeking to screen for nucleic acid inhibitors capable of inhibiting HAV IRES elements would have been motivated to use the teachings of the claims in the '985 patent on methods of screening for any potential anti-HAV agent capable of interacting with a HAV IRES element and screen for nucleic acid inhibitors

because Draper et al. notes that nucleic acids complementary to viral sequences can serve as potent inhibitors of viral activity. It would have been obvious for the ordinary skilled artisan to screen for nucleic acid inhibitors complementary to the IRES elements because Draper et al. indicates that nucleic acid sequences (antisense) can be effective inhibitors of viral activity. Given the teachings of the claims in the '985 patent and the level of skill of the ordinary skilled artisan at the time of the invention was made, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim 3 is directed to an invention not patentably distinct from claims 1,6 and 14 of commonly assigned U.S. Patent 5,738,985. Specifically, the claims are rejected for reasons recited in the above obviousness type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. 5,738,985, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior

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inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Any rejections not repeated in this Office Action are withdrawn.

Claim 18 is allowed.

Claims 8-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be sent directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding or relating to attachments to this Office Action should be directed to the receptionist whose telephone number is (703) 305-3291.

David Guzo
September 19, 2002

DAVID GUZO
PRIMARY EXAMINER
David Guzo